K133177

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510(k) Summary

Summary Date: January 30, 2014

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Trade Name: Modified HD Guide Catheter

Common Name: Percutaneous Catheter

Classification Name: Percutaneous Catheter, 21CFR 870.1250 – Class II

Product Code: DQY and DQO

Legally Marketed Predicate Devices:

Reference (Clearance Date)	Device
K090335 (May 6, 2009)	Concentric HD Guide Catheter
K110483 (April 4, 2011)	Modified HD Guide Catheter
K112404 (March 15, 2012)	Concentric Balloon Guide Catheter

Device Description: The Modified HD Guide Catheters are single lumen, braided, variable stiffness shaft catheters designed for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary or neuro vascular system. The catheters include a radiopaque marker on the distal end for angiographic visualization and a luer hub on the proximal end allowing attachments for flushing and aspiration. The catheter shaft has a hydrophilic coating to reduce friction during use. A rotating hemostatic valve with side-arm adapter is provided with each catheter.

Accessories:

The Modified HD Guide Catheter is packaged with a Rotating Hemostasis Valve.

Indications for Use / Intended Use:

The proposed Indications for Use are as follows:

The Modified HD Guide Catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary and neuro vascular systems. It may also be used as a diagnostic angiographic catheter and as a conduit for retrieval devices.

Technological Characteristics and Product Feature Comparison:

The subject device has the same technological characteristics as the predicate devices (**K090335** and **K110483**). The device design, materials, fundamental scientific technology, materials and processes for packaging and sterilization have not been changed from the previous predicate devices (**K090335** and **K110483**). The subject device differs from the predicate device, **K112404** primarily in that it does not include a balloon at the distal tip or a second lumen.

A tabular comparison of the specific technological characteristics between the predicate devices and subject device is provided below.

Product Feature Comparison of Subject Device with Predicate Devices

Feature	Predicate Device, K112404	Predicate Device, K090335	Predicate Device, K110483	Subject Device
Indications for Use	The Concentric Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices	The HD Guide Catheter is indicated for the removal/aspiration of fresh, soft emboli and thrombi from vessels in the arterial system.	The Modified HD Guide Catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary and neuro vascular systems. It may also be used as a diagnostic angiographic catheter.	The Modified HD Guide Catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary and neuro vascular systems. It may also be used as a diagnostic angiographic catheter and as a conduit for retrieval devices.

Feature	Predicate Device, K112404	Predicate Device, K090335	Predicate Device, K110483	Subject Device
Device Description	The Concentric Balloon Guide Catheters are coaxial-lumen, braid-reinforced, variable stiffness catheters designed for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. A radiopaque marker is included on the distal end for angiographic visualization. A compliant balloon is mounted on the distal end to provide temporary vascular occlusion during angiographic procedures. A bifurcated luer hub on the proximal end allows attachments for flushing, inflation and aspiration. Balloon Guide Catheter dimensions and maximum recommended balloon inflation volume are indicated on product label. If indicated on product label, a dilator is provided.	The HD Guide Catheter consists of a single lumen, braided, variable stiffness shaft with a radiopaque marker on the distal end and a luer hub on the proximal end. The catheter shaft has a hydrophilic coating to reduce friction during use. A rotating hemostatic valve with side-arm adapter is provided with each catheter.	Same as predicate device, K090335	Same as predicate devices, K090335 and K110483

Feature	Predicate Device, K112404	Predicate Device, K090335	Predicate Device, K110483	Subject Device
Outer Jacket	Pebax®	Pebax®	Same as predicate device, K090335	Same as predicate devices, K090335 and K114083
Braid	Stainless Steel	Stainless Steel	Same as predicate device, K090335	Same as predicate devices, K090335 and K114083
Strain Relief	Polyolefin	Polyolefin	Same as predicate device, K090335	Same as predicate devices, K090335 and K114083
Braid distal end securement	PTFE	PTFE	Same as predicate device, K090335	Same as predicate devices, K090335 and K114083
Catheter Hub	Polyurethane	Pebax	Same as predicate device, K090335	Same as predicate devices, K090335 and K114083
Marker Band	Platinum/Iridium	Platinum/Iridium	Same as predicate device, K090335	Same as predicate devices, K090335 and K114083
Adhesive	Acrylic (Acrylated Urethane)	Acrylic (Acrylated Urethane)	Same as predicate device, K090335	Same as predicate devices, K090335 and K114083
Outer jacket coating	NA	hydrophilic coating	Same as predicate device, K090335	Same as predicate devices, K090335 and K114083
Labeled Shaft Outer Diameter	7F - 9F	3.9F - 5.2F	6.3F	Same as predicate devices, K090335 and K114083
Effective Lengths	80cm or 95cm	115 cm – 136 cm	105-120 cm	Same as predicate devices, K090335 and K114083
Accessory Devices Provided	Dilator	Rotating Hemostatic Valve	Same as predicate device, K090335	Same as predicate devices, K090335 and K114083
Packaging Materials and Configuration	Polyethylene Tube and HDPE Packaging Card	Polyethylene Tube and HDPE Packaging Card	Same as predicate device, K090335	Same as predicate devices, K090335 and K114083
Sterilization Method	EO Sterilization	Same	Same	Same
How Supplied	Sterile, Single Use	Same	Same	Same

Risk Assessment

Risk assessment of the Modified HD Guide Catheter has been conducted in accordance with EN ISO 14971:2012. As a result of the risk assessment, the Instructions for Use have been revised to include recommended aspiration procedure steps for use of the Modified HD Guide Catheter with retrieval devices.

Testing and Non-Clinical Performance Data:

The results of verification and validation conducted on the Modified HD Guide Catheter demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the predicate devices (**K090335 and K110483**). The same performance standards, specifications and results as those submitted in the predicate devices (**K090335** and **K110483**) are applicable to the subject device because the designs are identical and no changes have been made to the design, materials, processes, or packaging materials as a result of the expanded indications for use. Therefore, the following design verification tests submitted in the predicate devices (**K090335** and **K110483**) are applicable to the subject device and its new indications for use:

- Tip Patency during Aspiration: the ability of the device tip to maintain patency during aspiration during simulated use testing was successfully evaluated.
- Air Leak Resistance during Aspiration: the ability of the device to resist leakage during aspiration was successfully evaluated.
- Leak Testing: the ability of the device to resist leakage was successfully evaluated.
- Dimensional Testing: dimensions of the device were successfully verified.
- Tensile Testing: the tensile strength of the device was successfully evaluated.
- Kink Resistance Testing: the ability of the device to withstand curves without kinking was successfully evaluated.
- Flexural Fatigue Testing: the flexural fatigue tolerance of the device was successfully evaluated.
- Torque Testing: the ability of the device to withstand torsional forces was successfully evaluated.
- Tip Flexibility Testing: the force to deflect the catheter tip was successfully evaluated.
- Coating Lubricity and Durability Testing: the durability of the hydrophilic coating was successfully evaluated.
- Flow Rate Testing: the rate of flow through the device lumen was successfully evaluated.
- Luer Testing: luer integrity and conformance to luer standards was successfully evaluated.

To support the expansion of the Indications for Use (IFU), performance testing utilized design validation / simulated use testing to confirm that the subject device and accessories meets user needs "as a conduit for retrieval devices" and continue to meet design requirements of the predicate device. Simulated use testing evaluates the device's ability to be used in a neurovascular model per procedural instructions outlined in the modified Instructions for Use. Based on the results of the risk assessment, no other testing was required to demonstrate the device meets intended uses.

Design validation/simulated use testing was conducted using a neurovascular model cast from actual human neurovascular arteries. This bench testing model replicates the tortuosity, diameter and location of the arteries in the neurovasculature. The model incorporates a re-circulating water bath at 37°C pressurized between 2 – 2.5 psi (100 – 126 mm Hg) to simulate the human arterial circulation.

The simulated use tests described in **Table 2** were conducted in support of the expanded indications for use. Finished sterilized devices were used for the simulated use testing. All design validation testing followed the procedural instructions outlined in the Instructions for Use which was revised to include a "Recommended Aspiration Procedure" for use with retrieval devices. Based on the successful completion of the testing, the subject device and its accessories have met all of the pre-specified requirements. A summary of the design validation / simulated use testing and the results is described in **Table 2** below.

Table 2: Design Validation / Simulated Use Testing of Subject Device and Accessories

Test	Test Method Summary	Results
Tip Patency during Aspiration	Purpose: Tip patency is evaluated in a neurovascular model to verify that the distal tip of catheter remains patent during vigorous aspiration to avoid loss of suction at the distal tip. Method: A neurovascular model is placed in a re-circulating water bath at 37°C and pressurized to simulate human arterial circulation. The catheter is placed in the model to a specified location following procedural instructions outlined in the Instructions for Use. The catheter is aspirated vigorously using a 60 cc syringe and the shape of the distal tip is visually verified to determine if distal tip remains patent during aspiration.	Pass All samples met acceptance criteria for expanded indications for use. Device continues to meet same design requirements as predicate devices (K090335 and K110483).
Lumen Compatibility	Purpose: Lumen compatibility is evaluated in a neurovascular model to verify that guidewires and other devices shall pass through the inner shaft of the catheter with no more than moderate resistance. Method: A neurovascular model is placed in a re-circulating water bath at 37°C and pressurized to simulate human arterial circulation. The catheter is placed in the model to a specified location following procedural instructions outlined in the Instructions for Use. A "compatible device" is inserted through the inner shaft of the catheter and assessed for degree of resistance through inner shaft, i.e., easy, moderate, difficult, or not possible.	Pass All samples met acceptance criteria for expanded indications for use. Device continues to meet same design requirements as predicate devices (K090335 and K110483).

Test	Test Method Summary	Results
Lumen and Retriever Compatibility	Purpose: Lumen and Retriever compatibility is evaluated in a neurovascular model to verify that the Retriever and microcatheter (as a system) is able to be withdrawn through the catheter and completely removed from the model without device fracture. Method: A neurovascular model is placed in a re-circulating water bath at 37°C and pressurized to simulate human arterial circulation. The Retriever and microcatheter is inserted through the catheter to reach a specified target location following procedural instructions outlined in the Instructions for Use. The Retriever and microcatheter (as a system) is pulled back through the catheter and completely remove them from the model. The Retriever is visually inspected for damage.	Pass All samples met acceptance criteria for expanded indications for use. Device continues to meet same design requirements as predicate devices (K090335 and K110483).
Infusion and Aspiration	Purpose: Infusion and aspiration of the catheter is evaluated in a neurovascular model to verify that the user is able to aspirate and inject fluid thru the Extension Tubing with 60cc syringe. Method: A neurovascular model is placed in a re-circulating water bath at 37°C and pressurized to simulate human arterial circulation. The catheter is placed in the model to a specified location following procedural instructions outlined in the Instructions for Use. The Retriever and microcatehter are advanced (as a system) through the BGC. The extension tubing is attached to the Y-arm of the rotating hemostasis valve. Fluid is infused vigorously through extension tubing with a 60cc syringe. While retracting both the Retriever and microcatheter (as a system) through the catheter to completely remove the system from the model, a 60cc syringe is used to aspirate through the extension tubing. When the Retriever is retracted into the catheter tip, the user aspirates to 60cc's vigorously as the Retriever is fully retracted in the catheter. The catheter is visually inspected for damage.	Pass All samples met acceptance criteria for expanded indications for use. Device continues to meet same design requirements as predicate devices (K090335 and K110483).

Test	Test Method Summary	Results
Distal tip stability	Purpose: Distal tip stability is evaluated in a neurovascular model to verify that the distal tip does not move during retraction of the Retriever and microcatheter (as a system) into the catheter. Method: A neurovascular model is placed in a re-circulating water bath at 37°C and pressurized to simulate human arterial circulation. The catheter is placed in the model to a specified location following procedural instructions outlined in the Instructions for Use. The Retriever and microcatehter are advanced (as a system) through the catheter. The extension tubing is attached to the Y-arm of the rotating hemostasis valve. Fluid is infused vigorously through extension tubing with a 60cc syringe. While retracting both the Retriever and microcatheter (as a system) through the catheter to completely remove the system from the model, a 60cc syringe is used to aspirate through the extension tubing. When the Retriever is retracted into the catheter tip, the user aspirates to 60cc's vigorously as the Retriever is fully retracted in the catheter. The catheter is visually inspected for damage. The distal tip of catheter is visually inspected to verify it does not move forward or back during retraction of the Retriever and microcatheter (as a system).	Pass All samples met acceptance criteria for expanded indications for use. Device continues to meet same design requirements as predicate devices (K090335 and K110483).
Mechanical and Functional Integrity	Purpose: The catheter is inspected for mechanical and functional integrity following simulated use in a neurovascular model to verify that the catheter maintains mechanical integrity (e.g., visible damage, shaft kink, hub joints, shaft joints, tip separation, corrosion) and that catheter function was not impaired by the introducer sheath. Method: A neurovascular model is placed in a re-circulating water bath at 37°C and pressurized to simulate human arterial circulation. The catheter is placed in the model to a specified location following procedural instructions outlined in the Instructions for Use. The Retriever and microcatehter are advanced (as a system) through the catheter. The extension tubing is attached to the Y-arm of the rotating hemostasis valve. Fluid is infused vigorously through extension tubing with a 60cc syringe. While retracting both the Retriever and microcatheter (as a system) through the catheter to completely remove the system from the model, a 60cc syringe is used to aspirate through the extension tubing. When the Retriever is retracted into the catheter tip, the user aspirates to 60cc's vigorously as the Retriever is fully retracted in the catheter. The catheter is visually inspected for mechanical and functional damage.	Pass All samples met acceptance criteria for expanded indications for use. Device continues to meet same design requirements as predicate devices (K090335 and K110483).

Test	Test Method Summary	Results
Retriever Fracture	Purpose: Retriever fracture is evaluated in a neurovascular model to verify that the Retriever is free from fractures following simulated use testing. Method: A neurovascular model is placed in a re-circulating water bath at 37°C and pressurized to simulate human arterial circulation. The catheter is placed in the model to a specified location following procedural instructions outlined in the Instructions for Use. The Retriever and microcatehter are advanced (as a system) through the catheter. The extension tubing is attached to the Y-arm of the rotating hemostasis valve. Fluid is infused vigorously through extension tubing with a 60cc syringe. While retracting both the Retriever and microcatheter (as a system) through the catheter to completely remove the system from the model, a 60cc syringe is used to aspirate through the extension tubing. When the Retriever is retracted into the catheter tip, the user aspirates to 60cc's vigorously as the Retriever is fully retracted in the catheter. The catheter is visually inspected for damage. The Retriever is removed from the microcatheter and visually inspected for fractures.	Pass All samples met acceptance criteria for expanded indications for use. Device continues to meet same design requirements as predicate devices (K090335 and K110483).
Liquid leak resistance	Purpose: Liquid leak resistance of the catheter is evaluated in a neurovascular model to verify that the catheter does not leak from the shaft or hub/shaft interface during use. Method: A neurovascular model is placed in a re-circulating water bath at 37°C and pressurized to simulate human arterial circulation. The catheter is placed in the model to a specified location following procedural instructions outlined in the Instructions for Use. The Retriever and microcatehter are advanced (as a system) through the catheter. The extension tubing is attached to the Y-arm of the rotating hemostasis valve. Fluid is infused vigorously through extension tubing with a 60cc syringe. While retracting both the Retriever and microcatheter (as a system) through the catheter to completely remove the system from the model, a 60cc syringe is used to aspirate through the extension tubing. When the Retriever is retracted into the catheter tip, the user aspirates to 60cc's vigorously as the Retriever is fully retracted in the catheter. The catheter is visually inspected for leaks from the shaft or hub/shaft interface during use.	Pass All samples met acceptance criteria for expanded indications for use. Device continues to meet same design requirements as predicate devices (K090335 and K110483).

Based on conformance with these test requirements, the Modified HD Guide Catheter is as safe, as effective, and performs as well as or better than the legally marketed predicate devices (**K090335** and **K110483**).

Clinical Performance Data:

To demonstrate substantial equivalence, a review of the Thrombectomy REvasculatorization of large Vessel Occlusions in acute ischemic stroke (TREVO) 2 IDE study and the TREVO post market study in Europe was conducted to assess if thrombectomy procedures performed with the Modified HD Guide Catheter as a support catheter have similar revascularization rates as published trials and to identify any Modified HD Guide Catheter specific safety events which may preclude expansion of the indications for use "as a conduit for retrieval devices." Clinical data was also reviewed to identify if any of the procedure events were reported to be directly related to the Modified HD Guide Catheter, also marketed as the Distal Access Catheter (DAC).

TREVO 2 Study

The TREVO 2 study was an IDE trial designed to support FDA clearance of the Trevo Retriever in the U.S. The study enrolled 178 subjects between February 3, 2011 and December 1, 2011 at 26 sites in the United States and one site in Spain. A review of the TREVO 2 data showed that DAC was used in a total of 99 patients. For all 99 patients, the DAC was placed for additional support at the proximal face of the thrombus in the intracranial artery and used as a conduit during the retrieval procedure.

The overall review of the DAC 99 cohort in the TREVO 2 study, showed that safety and efficacy of the thrombectomy procedure was similar to the overall TREVO 2 study population. The total procedure length, time from the first retrieval device to the final angiogram and number of thrombectomy device passes in this DAC cohort are similar to the TREVO 2 data illustrating that the additional step of using the DAC does not affect the procedure time. In the 99 patients where DAC was used during the retriever procedure, no complaints were attributed specifically to the DAC. The microcatheters were able to track through the DAC to the clots in the majority of the cases. The revascularization rate in these patients was 84.8% and showed that successful revascularization was possible using DAC as a conduit for retrieval devices. There were no reports or findings that procedural events were related to DAC therefore supporting safety of DAC during thrombectomy procedures.

TREVO Study

The TREVO study was a post marketing prospective, multi-center, single arm study performed at seven sites in Europe and was designed to determine the revascularization rate of the CE-marked Trevo device in large vessel occlusions in ischemic stroke patients. Sixty (60) patients were enrolled between February, 2010 and August, 2011.

Review of the TREVO data showed DAC was used as an insertion and guidance catheter in a total of 34 patients. Further review of these 34 patients showed that aspiration through DAC was applied in 30 patients during withdrawal of the Trevo device. To support the aspiration step during the withdrawal of the Trevo retriever, data was reviewed for this 30 TREVO patient cohort. For all 30 patients the DAC was placed at or near the proximal face of the thrombus in the intracranial artery.

The overall review of the DAC cohort in the TREVO study, showed that safety and efficacy was similar to the overall study population. The mean procedure time was not increased by the additional step of applying adjunctive aspiration during the withdrawal of the retriever. Although this is a small cohort, a high revascularization rate of 96.7% was observed. The ten point improvement in NIHSS at 24 hours and 7 days also supports the utility of the DAC adjunctive aspiration during withdrawal of the retriever device. None of the procedure related or CEC adjudicated events were related to DAC which supports the safety of the DAC during thrombectomy procedures.

Post-Market Sureillance

In addition to the data review of the TREVO2 and TREVO trials, a review of post market surveillance product complaints and Medical Device Reports (MDRs) was conducted to assess the top complaints reported for DAC and to assess total number of reportable events. The top device complaints for the DAC are catheter kinks, lumen collapse or ovalization which is consistent with complaints routinely reported with this class of access devices. The overall complaint rate for device problem or patient effect is low for DAC (0.21%).

A review of the MDRs for DAC identified a total of 10 MDRs filed from 2008 to July 31, 2013. The overall number of reportable events was small and no new risks were identified from the post market surveillance database and the MAUDE database.

Literature Review

Literature was searched pertaining to DAC use in acute ischemic stroke to support safety of DAC during thrombectomy procedures. A total of 15 published articles were reviewed. The literature search showed that DAC is often used during thrombectomy procedures in acute ischemic stroke patients and is a contributory factor to the overall success of the procedure. DAC provides support in difficult distal anatomy and allows adjunctive aspiration during withdrawal of the retriever from the vessel. Studies showed that the revascularization rates in patients with DAC are similar or better to the acceptable revascularization rates for thrombectomy procedure. There were no unanticipated adverse events reported from using DAC. The literature supports safety and efficacy of DAC during thrombectomy procedures.

Conclusion:

The review of TREVO 2 and TREVO clinical trials, literature and post-market data showed that the Modified HD Guide Catheter is used often during thrombectomy procedures with comparable revascularization rates to previously reported results and no new patient risks were identified. The device provides better access to distal anatomy and support to the microcatheter and retrieval devices during insertion and allows aspiration of clots during withdrawal of the retriever device.

Summary of Substantial Equivalence:

Because the proposed expansion in indications for use for the Modified HD Guide Catheter does not alter the fundamental scientific technology of the predicate devices; and because risk assessments and successful validation testing and review of the clinical data from TREVO2 and TREVO studies, literature and post-market data raise no new questions of safety and effectiveness, Concentric Medical has determined that the Modified HD Guide Catheter with the expanded indications for use to be as safe, as effective, and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

Concentric Medical, Inc.
% Ms. Rhoda Santos
Principal Regulatory Affairs Specialist
301 E. Evelyn Avenue
Mountain View, CA 94041

Re: K133177
Trade/Device Name: Concentric HD Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Additional product code: DQO
Dated: November 26, 2013
Received: November 27, 2013

Dear Ms. Santos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Peña -S

Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133177

Device Name
Concentric HD Guide Catheter

Indications for Use *(Describe)*
The Concentric HD Guide Catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary and neuro vascular systems. It may also be used as a diagnostic angiographic catheter and as a conduit for retrieval devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos D Pena -S

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